K972109

510(k) Summary

NOV 14 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92(c).

1.Contact Person

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2.Date Summary Prepared

6/4/97

3.Trade Name

Spacemaker® Surgical Balloon Dissector/Expander

4.Common Name

Surgical Balloon Dissector/Expander

5.Predicate Devices

K951878	Spacemaker® and Spacemaker® II Surgical Balloon Dissector with and without Cannula
K904265	Inamed Ruiz-Cohen Intraoperative Expander
K862203	McGhan Magna-Site™ Tissue Expander
K843704	McGhan Tissue Expander

6.Device Description

The Spacemaker® Surgical Balloon Dissector/Expander device is a handheld, manually manipulated surgical balloon device which dissects tissue planes, intraoperatively and subsequently expands the overlying tissue. This device is a temporary subcutaneous or submuscular implant device. The Spacemaker® Surgical Balloon Dissector/Expander is a single use, disposable device provided sterile to the

physician. The major components of the device are a balloon dissector and an injection port/connector.

7.Intended Use

The intended use of the Spacemaker® Surgical Balloon Dissector/Expander is to create a surgical space anywhere in the body by dissecting layers of connective tissue along natural planes of separation and provide intraoperative and subsequent tissue expansion. The Spacemaker® Surgical Balloon Dissector/Expander is a temporary subcutaneous or submuscular implant device. The indications for use include the following: breast reconstruction, limb reconstruction, correction of congenital deformities and cosmetic defects, and scar revision.

8.Comparison to Predicate Devices

The claim of substantial equivalence is based on the fact that the GSI Spacemaker® Surgical Balloon Dissector/Expander has the same principle of operation and intended uses as the predicate device. These differences do not raise additional questions regarding safety or efficacy compared to the predicate devices. Therefore, it can be concluded that the Spacemaker® Surgical Balloon Dissector/Expander is substantially equivalent to the predicate devices.

The following table lists the similarities and differences between the Spacemaker® Surgical Balloon Dissector/Expander and predicate devices.

DEVICE POINT OF COMPARISON	SPACEMAKER® & SPACEMAKER®II DISSECTOR WITH & W/OUT CANNULA (K951878)	INAMED RUIZ-COHEN INTRAOPERATIVE TISSUE EXPANDER (K904265)	MCGHAN MAGNA-SITE™ TISSUE EXPANDER (K862203)	MCGHAN TISSUE EXPANDER (K843704)	SPACEMAKER® SURGICAL BALLOON DISSECTOR/ TISSUE EXPANDER
Intended Use	Dissect layers of connective tissue along natural planes of separation	Intraoperative tissue expansion	Tissue expansion	Tissue expansion	Dissect layers of connective tissue along natural planes of separation & provide intraoperative & subsequent tissue expansion
Indications	Any area of the body where it is necessary to separate the layers of connective tissue for surgical access	Where rapid creation of a tissue flap is needed in a single surgical session for scar revision or other skin defects	Post mastectomy reconstruction, augmentation and scar revision	Post mastectomy reconstruction, augmentation and scar revision	Breast reconstruction, limb reconstruction, correction of congenita deformities and cosmetic defects, and scar revision
Examples of Under-lying Procedures Associated with Surgical Dissection (Expansion) Specified in the Labeling	General, laparoscopic, endoscopic, plastic and reconstructive, including aesthetic, surgery	Unknown	Unknown	Unknown	General, laparoscopic, endoscopic, plastic an reconstructive, including aesthetic, surgery
How Supplied	Single patient use, disposable	Unknown	Single use	Single use	Single patient use, disposable
Principle of Operation	Handheld, manually manipulated surgical dissector	Handheld, manually manipulated tissue expander	Handheld, manually manipulated tissue expander	Handheld, manually manipulated tissue expander	Handheld, manually manipulated surgical dissector/expander
Balloon Volume Range	10-2500cc saline or air inflation	0.8-40cc saline (from catalog and Instructions for Use)	50-800cc	Range of sizes (and shapes)	1-2500cc saline or air inflation
Balloon Shapes	Include kidney, clover, horseshoe, semi-round and U-shaped profiles	Cylindrical and spherical (from catalog)	Round and rectangular	Range of (sizes and) shapes	Range of (sizes and) shapes
Balloon Function	Balloon dissector	Balloon expander	Balloon expander	Balloon expander	Balloon dissector/expander

Balloon Cover	Yes	No	No	No	Optional
Filling Communication for Temporary Implant	Not applicable	Not applicable	Injection port and connector	Injection port and connector	Injection port and connector
Port Detection Method	Not applicable	Not applicable	Palpation and magnetic	Palpation	Palpation
Duration of Expansion	Not applicable	Intraoperative, single surgical session	Temporary implantation; typically less than 90 days	Temporary implantation; less than 60 days	Temporary implantation; typically less than 90 days
Materials	Polymers, silicone and stainless steel	Silicone, polymers	Silicone, stainless steel	Silicone, stainless steel	Polymers, silicone and stainless steel
Packaging Configuration	With or without cannula	With blunt needle or stopcock	With or without injection port and connector	With or without injection port and connector	Without cannula, with o without injection port and connector

9. **Testing in Support of Substantial Equivalence:**

Specific ASTM tests relating to the design differences between the Spacemaker® Surgical Balloon Dissector/Expander and the predicate devices were performed to evaluate if the differences would raise new questions of safety or efficacy. The results of this testing indicated no new issues were raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Cathleen Mantor
Regulatory Affairs/Quality Assurance Manager
General Surgical Innovations
10460 Bubb Road
Cupertino, California 95014

NOV 14 1997

Re: K972109
Trade Name: Spacemaker® Surgical Balloon Dissector/Expander
Regulatory Class: Unclassified
Product Code: LCJ
Dated: September 26, 1997
Received: September 29, 1997

Dear Ms. Mantor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8.1 Statement of Indications for Use

510(k) Number (if known): K972109

Device Name

Spacemaker® Surgical Balloon Dissector/Expander

Indications for Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (per 21 CFR 801.109) OR Over-the-Counter Use ___ (Optional format 2Jan96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972109